

AMENDMENTS

In the Claims:

1. (Currently Amended) A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce ~~that~~ the protein, comprising the steps of:

(a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by applying the first extract to the skin of the newborn dog,

(b) after a period sufficient to allow the dog to establish an immune response to the first extract, challenging the dog with the first extract,

(c) observing the degree of a first allergic response provoked,

and if a detectable allergic response is observed, further performing the steps of:

(d) challenging the dog with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein, where the challenging is carried out in the same manner as the challenging with the first extract in step (b).

(e) observing the degree of a second allergic response provoked by the second extract.

(f) comparing the degree of the first allergic response observed with that observed the degree of the second allergic response by carrying out steps (a) (e) above, but where the sensitizing step (a) or challenging step (b) is carried out with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein wherein the challenging (b) and observing (e) steps are carried out in the same manner for both the first and second extracts, and

(g e) if the degree of the first allergic response at (e) is greater than ~~that observed the~~ degree of the second allergic response by carrying out steps (a) (e) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans.

2. (Currently Amended) The method of claim 1, wherein said challenging and observing steps are selected from the group consisting of:

(a) applying the first and ~~or~~ the second extract to a skin region of the dog and observing a local wheal reaction at the application site as the allergic response (skin test);

(b) feeding the first and ~~or~~ the second extract to the dog, and observing gastrointestinal upset as the allergic response (feeding test);

B¹ (c) injecting the first and ~~or~~ the second extract directly with the wall of the stomach of the dog and observing a local wheal reaction at the application site as the allergic response (gastroendoscopy test);

(d) administering the first and ~~or~~ the second extract by inhalation to the dog, and observing bronchial constriction as the allergic response (inhalation test); and

(e) applying the first and ~~or~~ the second extract with a patch immobilized on the skin and observing inflammation at the site of application (transdermal patch test).

B² 3. (Currently Amended) The method of Claim 1, wherein the second extract is obtained from a genetically modified transgenic plant.

N¹ 4. (Previously Amended) The method of claim 3, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

B³ 5. (Currently Amended) The method of claim 1, wherein step ~~(d) is carried out by~~ applying the first extract to a dog sensitized with said second extract (a) further comprises sensitizing the newborn dog with the second extract by applying the second extract to the skin of the newborn dog.

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6. (Currently Amended) The method of claim 1, wherein substantially no allergic reaction is observed in ~~carrying out steps (a)-(c) and (e) in step (d)~~.

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7. (Previously Amended) The method of claim 1, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

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8. (Currently Amended) The method of claim 1, ~~which~~ wherein the identification of a potential allergen in step (g), further includes, when a potential allergen is identified in step (e), repeating step (e) comprises the steps of:

(h) challenging the dog with the heterologous protein in purified form, and

(i) observing the degree of allergic response provoked.

9. Canceled.

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10. (Currently Amended) The method of claim 8, wherein the heterologous protein in purified form is ~~produced by~~ obtained from a transgenic plant.

11. Canceled.

B⁷
12. (Currently Amended) The method of claim 1, wherein the degree of allergic response observed in step (c), compared with that observed in step (e d) is indicative of the degree of allergenicity expected in humans.

Claims 13-21 have been withdrawn.

22. (Currently Amended) A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce that the protein, comprising the steps of:

(a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by injecting the first extract into the newborn dog,

(b) after a period sufficient to allow the dog to establish an immune response to the first extract, challenging the dog with the first extract,

(c) observing the degree of allergic response provoked,

and if a detectable allergic response is observed, further performing the steps of:

(d) challenging the dog with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein, where the challenging is carried out in the same manner as the challenging with the first extract in step (b),

(e) observing the degree of a second allergic response provoked by the second extract,

(f) comparing the degree of the first allergic response observed with that observed the degree of the second allergic response by carrying out steps (a) (c) above, but where the sensitizing step (a) or challenging step (b) is carried out with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein wherein the challenging (b) and observing (c) steps are carried out in the same manner for both the first and second extracts, and

(g e) if the degree of the first allergic response at (e) is greater than that observed the degree of the second allergic response by carrying out steps (a) (c) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans.

23. (Currently Amended) The method of claim 22, wherein said challenging and observing steps are selected from the group consisting of:

(a) applying the first and ~~or~~ the second extract to a skin region of the dog and observing a local wheal reaction at the application site as the allergic response (skin test);

(b) feeding the first and ~~or~~ the second extract to the dog, and observing gastrointestinal upset as the allergic response (feeding test);

(c) injecting the first and ~~or~~ the second extract directly with the wall of the stomach of the dog and observing a local wheal reaction at the application site as the allergic response (gastroendoscopy test);

(d) administering the first and ~~or~~ the second extract by inhalation to the dog, and observing bronchial constriction as the allergic response (inhalation test); and

(e) applying the first and ~~or~~ the second extract with a patch immobilized on the skin and observing inflammation at the site of application (transdermal patch test).

24. (Currently Amended) The method of claim 23, wherein the second extract is obtained from a genetically modified transgenic plant.

25. (Previously Added) The method of claim 24, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

26. (Currently Amended) The method of claim 23, wherein step ~~(d) is carried out by applying the first extract to a dog sensitized with said second extract~~ (a) further comprises sensitizing the newborn dog with the second extract by injecting the second extract into the newborn dog.

27. (Currently Amended) The method of claim 23, wherein substantially no allergic reaction is observed in ~~carrying out steps (a)-(c) and (e) in step (d).~~

28. (Previously Added) The method of claim 23, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

29. (Currently Amended) The method of claim 23, ~~which~~ wherein the identification of a potential allergen in step (g), further includes, when a potential allergen is identified in step (e), repeating step (e) comprises the steps of:

(h) challenging the dog with the heterologous protein in purified form, and

(i) observing the degree of allergic response provoked.

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30. (Currently Amended) The method of claim 29, wherein the heterologous protein in purified form is ~~produced by~~ obtained from a transgenic plant.

31. (Currently Amended) The method of claim 23, wherein the degree of allergic response observed in step (c), compared with that observed in step (e d) is indicative of the degree of allergenicity expected in humans.

32. (Currently Amended) A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce ~~that~~ the protein, comprising the steps of:

(a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by feeding the first extract to the newborn dog,

(b) after a period sufficient to allow the dog to establish an immune response to the first extract, challenging the dog with the first extract,

(c) observing the degree of allergic response provoked,

and if a detectable allergic response is observed, further performing the steps of:

(d) challenging the dog with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein, where the challenging is carried out in the same manner as the challenging with the first extract in step (b).

(e) observing the degree of a second allergic response provoked by the second extract,

(f) comparing the degree of the first allergic response observed with that observed the degree of the second allergic response by carrying out steps (a) (e) above, but where the sensitizing step (a) or challenging step (b) is carried out with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein wherein the challenging (b) and observing (e) steps are carried out in the same manner for both the first and second extracts, and

(g) if the degree of the first allergic response at (e) is greater than that observed the degree of the second allergic response by carrying out steps (a) (e) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans.

33. (Currently Amended) The method of claim 32, wherein said challenging and observing steps are selected from the group consisting of:

(a) applying the first and ~~or~~ the second extract to a skin region of the dog and observing a local wheal reaction at the application site as the allergic response (skin test);

(b) feeding the first and ~~or~~ the second extract to the dog, and observing gastrointestinal upset as the allergic response (feeding test);

(c) injecting the first and ~~or~~ the second extract directly with the wall of the stomach of the dog and observing a local wheal reaction at the application site as the allergic response (gastroendoscopy test);

(d) administering the first and ~~or~~ the second extract by inhalation to the dog, and observing bronchial constriction as the allergic response (inhalation test); and

(e) applying the first and ~~or~~ the second extract with a patch immobilized on the skin and observing inflammation at the site of application (transdermal patch test).

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34. (Currently Amended) The method of claim 32, wherein the second extract is obtained from a genetically modified transgenic plant.

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35. (Previously Added) The method of claim 34, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

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36. (Currently Amended) The method of claim 32, wherein step ~~(d)~~ is carried out by applying the first extract to a dog sensitized with said second extract (a) further comprises sensitizing the newborn dog with the second extract by feeding the second extract to the newborn dog.

37. (Currently Amended) The method of claim 32, wherein substantially no allergic reaction is observed in ~~carrying out~~ steps ~~(a)-(c)~~ and (e) in step (d).

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38. (Previously Added) The method of claim 32, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

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39. (Currently Amended) The method of claim 32, ~~which~~ wherein the identification of a potential allergen in step (g), further includes, when a potential allergen is identified in step (e), repeating step (e) comprises the steps of:

(h) challenging the dog with the heterologous protein in purified form, and

(i) observing the degree of allergic response provoked.

40. (Currently Amended) The method of claim 39, wherein the heterologous protein in purified form is ~~produced by~~ obtained from a transgenic plant.

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41. (Currently Amended) The method of claim 32, wherein the degree of allergic response observed in step (c), compared with that observed in step (e ~~d~~) is indicative of the degree of allergenicity expected in humans.
